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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,708	07/14/2003	Frank Beerwerth	N98100026/P025	4185
9629	7590	12/15/2005	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			VERBITSKY, GAIL KAPLAN	
			ART UNIT	PAPER NUMBER
			2859	

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/617,708

Applicant(s)

BEERWERTH ET AL.

Examiner

Gail Verbitsky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10 and 12-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-10 and 12-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 4, 7-9, 14, 17, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by lushi et al. (U.S. 5017018) [hereinafter lushi].

lushi discloses a tympanic thermometer insertable into a cavity of a living body, the thermometer comprising a probe cap 6a and 6b shown in Figs. 7a and 8a. The cap/base body 6a is shaped to fit the body cavity (ear canal) and having a thin plate (film) window transparent to IR and attached to the cap (col. 8, lines 5-10). The base body 6a includes at least one air chamber (heat insulative air gap) 13 to provide/ improve the heat insulation between the body cavity and the temperature probe. The base body can also be formed of polysterene foam (col. 8, line 3), as the base body 6b, thus, inherently having air chambers/ pores. The caps 6a, 6b can be removable and thus, inherently, disposable (replaceable). The caps comprise lugs 60 holding/ clamping the cap to the probe/ probe holder. It is, inherent, that the pores/ chambers are separated by thin walls/ fins which are, inherently, made of the same, plastic, material.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2, 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over lushi in view of Wortz.

lushi discloses the device as stated above.

Although lushi states that the insulation is a plastic foam, lushi does not explicitly teach that the insulation is a soft plastic foam, as stated in claim 2, in combination with the remaining limitations of claims 15-16.

Wortz discloses a device in the field of applicant's endeavor wherein the insulation made a closed cell (closed pores) soft and, inherently, porous foam (foamed rubber or polyurethane) 94 so as to better conform the ear canal.

For claim 16: it is, inherent, that being a soft foam, as claimed by applicant, the cap is not completely shaped/ stretched prior to insertion to the ear canal, but only when it is placed over the probe. Therefore, the cap can, at least partially expand/ stretch to obtain the necessary shape only when it is placed over the probe to fit the body cavity, and thus, not prior to being positioned onto the probe.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to replace the insulation material, disclosed by lushi, with a foam insulation made of polyurethane (soft), as taught by Wortz, so as to make the cap soft and more comfortable for patient, especially for the patients with a painful inflammatory process.

7. Claims 9-10, 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iushi and Wortz as applied to claims 2, 15-16 above, and further in view of Lin.

Iushi and Wortz disclose the device as stated above.

They do not teach the limitations of claim 12. They do not explicitly teach the window film that being stretched by means of a holding device by clamping.

Lin discloses in Figs. 5, 8 a device wherein a window film 83 is held by means of an annular holding device A, which is clamped to a tubular body B (the numerals A-B have been added by the Examiner, see attachment to the previous Office action, 03/11/2004).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the holding device, disclosed by Iushi and Wortz, so as to have clamps to clamp the film to the tubular body (plastic tube), as taught by Lin, so as to provide a better stretch of the film over the window, in order to eliminate wrinkles, and thus, to provide more accuracy in measurements.

5. Claims 13, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iushi in view of Bohrn et al. (U.S. 4775586) [hereinafter Bohrn].

Iushi discloses a device as stated above.

Iushi does not explicitly teach the limitations of claims 13 and 18.

Bohrn teaches that using a method of hot pressing for a film, a desired transparency to an electromagnetic radiation (including IR) could be obtained.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to use a method of pressing, to provide a window of the

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device disclosed by, with a desired transparency to IR, as taught by Bohrn, because, since this method is commonly used to obtain a desired transparency, it involved less manufacturing costs than a new method.

6. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over lushi in view of Suszynski (U.S. 4863281).

lushi discloses a device as stated above.

lushi does not explicitly teach the limitations of claims 5-6.

Suszynski discloses in Fig. 2 a device/ disposable protective probe cover/ cap 19 in the field of applicant's endeavor comprising a probe cover substrate 21 bounded to a resilient (flexible/ stretchable) plastic film 25 covering the substrate on its outside surface.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device, disclosed by lushi, so as to have a flexible plastic film over a substrate (polysterene foam insulation) of the cap, as taught by Suszynski, so as to reinforce the cap by adding a flexible, and thus, not easily breakable, film.

Response to Arguments

8. Applicant's arguments with respect to claims 1-2, 4-9-10, 12-19 have been considered but are moot in view of the new ground(s) of rejection necessitated by the present amendment.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art cited in the PTO-892 and not mentioned above disclose related devices and methods.

Ferrari U.S. 5348397 discloses in Fig. 1 a temperature probe comprising a disposable probe cover 25 having an adhesive base 26 and a foamed (soft/ porous) plastic thermal insulation 27, inherently, having pores/ closed air chambers between the body cavity and the probe when the probe is inserted into the cavity.

Seacord U.S. 5167235 discloses in Figs. 1c and 2 a device/ disposable protective cap for a temperature-measuring probe introducible in an ear cavity. The cap comprises a base body (flexible plastic sheath) 16 shaped to fit a tympanic cavity and having an IR transparent window at end 42. The base body 16 also provided with an insulation 34. The window is a thin/ reduced thickness and transparent to IR. Seacord states that the insulation around the optical fiber can be a conventional polyethylene plastic foam (col. 5, line 29) fiber (probe) to further reduce any outside temperature effects. This would suggest making a cap comprising an insulation layer.

This would imply that the insulation has at least one closed pore (air chamber). Since it is very well known that air is a thermal insulation, it would imply, that a plurality of pores would add thermal insulative property and improve heat insulation. Although, Seacord states that the insulation 34 can be eliminated and, it appears that, as shown in Fig. 1c, the insulation 34 is bounded to the base body 16, Seacord is silent so as the thermal insulation 34 is a part of a disposable protective cap (attached to the cap 16). The fact

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that the cap is being stretched over the probe of the device, the probe is acting as a cap holder.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Verbitsky whose telephone number is 571/ 272-2253. The examiner can normally be reached on 7:30 to 4:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diego Gutierrez can be reached on 571/ 272-2245. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GKV

Gail Verbitsky

Primary Patent Examiner, TC 2800



November 28, 2005